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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,858	12/12/2005	Daniel Raederstorff	21478USWO (C0384435/0187	7897

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EXAMINER	
MCCORMICK, MELENIE LEE	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
04/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,858	RAEDERSTORFF ET AL.	
	Examiner	Art Unit	
	MELENIE MCCORMICK	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48,53 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28, 30-36, 28-48, and 53-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 February 2008 has been entered.

Claims 1-24, 29, 37, and 50-52 have been cancelled.

Claims 25-28, 30-36, 28-48, and 53-54 are pending and presented for examination on the merits.

Withdrawn Rejections

The previous rejection of claims 42-44 under 35 U.S.C. 102(e) as being anticipated by Gorsek (US 6,565,896) has been withdrawn in view of the amendments to claims 42-44.

The previous provisional obviousness type double patenting rejections 25-28, 30-36, 28-48, and 53-54 have been withdrawn in view of Applicant's amendments to the claims.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-28, 30-36, 38-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 5,922,756), Law et al. (JBC July 2002), Fluehmann et al. (US 6,784,207), and Cincotta et al. (US 5,714,519) with evidence provided by Pierce (1999).

A composition comprising EGCG and at least one of pantethine and phytanic acid, a method of making the composition, and a method of treatment of type I and type II diabetes comprising administering to a subject in need thereof a composition comprising EGCG and pantethine and phytanic acid is claimed.

Chan beneficially teaches that EGCG is an inhibitor of nitric oxide synthase (see e.g. col. 3, lines 23-25). Chan further teaches that an NO synthase may be involved in diabetes and therefore, catechin derivatives (including EGCG) may be helpful in treating the condition (see e.g. col 3, lines 51-56). Chan also beneficially teaches a method of treating diabetes which comprises administering to a mammal in need thereof EGCG

(See e.g. claims 1, 2, and 7). Chan further teaches that EGCG is in a pharmaceutical formulation presented in discrete unit dosages and that the discrete unit dosages may be capsules or tablets (solid unit dosages) (see e.g. col 4, lines 18-34). Chan also teaches that the EGCG is administered in a dose of 50 mg to 17.5 grams/day, which is within the dose range instantly claimed (see e.g. claim 6). Chan does not explicitly teach that phytanic acid or pantethine are included in this composition.

Law et al. also teaches that EGCG possesses anti-diabetic activity and can reduce blood glucose levels (see e.g. page 34939). Law et al. also teaches that insulin levels can be lowered with EGCG (see e.g. page 34933, second column).

Fluehmann et al. beneficially teach a composition for the treatment of diabetes comprising phytanic acid, a method of making the composition (see e.g. col 6, lines 1-5) and a method for the treatment of diabetes using phytanic acid (see e.g. col 1, lines 11-15). Fluehmann et al. also beneficially teach that the composition is in a unit dosage form, such as tablets or capsules (solid dosage forms) (see e.g. col 7, lines 57-61). Fluehmann et al. further teach that the amount of phytanic acid administered is within the dose range instantly claimed (about 0.1 to about 1000 mg, about 0.1 to about 500 mg or about 0.1 to 100 mg) (see e.g. claims 1, 4 and 5). Fluehmann also teaches that phytanic acid provides enhanced serum glucose clearance (see e.g. col 6, liens 46-53).

Cincotta et al. beneficially teach a method for the treatment of diabetes comprising administering to a subject in need thereof an effective amount of pantethine (see e.g. col 4, lines 26-34). Cincotta et al. also disclose that the dose range intended for use with this method is between 15 to about 500 mg/kg of body weight per day,

which is within the dose range instantly claimed (see e.g. col 5, lines 6-11 and claim 5). Cincotta et al. also teaches that pantethine reduces hyperglycemia (see e.g. col 5, lines 6-9).

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to admix EGCG, pantethine, phytanic acid and mixtures thereof in the dosage forms and amounts instantly claimed in order to make a composition for the treatment of diabetes. One of ordinary skill in the art would have been motivated to so based upon the disclosures of Chan, Law et al., Fluehmann et al., and Cincotta et al. that EGCG, phytanic acid and pantethine are useful in the treatment of diabetes in the same ranges of dose amounts and in the same forms instantly claimed. Based on the disclosure of Chan, Law et al., Fluehmann et al. and Cincotta et al. that each of the components is useful for treating diabetes, a person of ordinary skill in the art would have had a reasonable expectation of success in combining them to treat diabetes. It would further have been obvious to administer such a composition to a subject in need of treatment for diabetes, especially in view of the disclosure of methods for treatment disclosed by Chan, Law et al., Fluehmann et al., and Cincotta et al. which comprise administration of each component of the instantly claimed composition to a subject in need of diabetes treatment. A person of ordinary skill in the art would have had a reasonable expectation of success in treating both type I and type II diabetes with a combination of components taught by the cited referenced because it is understood in the art that both types of diabetes are characterized by hyperglycemia resulting from a relative deficiency in insulin, either through reduced insulin secretion or reduced insulin

action, or both (see e.g. page 161, second para). The adjustment of particular conventional working conditions (e.g. the particular result effective amounts of each component within the composition and the addition of the composition to a food or beverage) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 5,922,756), Law et al. (JBC July 2002), (Fluehmann et al. (US 6,784,207), and Cincotta et al. (US 5,714,519) with evidence provided by Pierce (1999) in view of Fischer (US 5,599,835), Pistolesi (WO 02/052955 A1) and Eriksson et al. (BioFactors).

Chan (US 5,922,756), Law et al. (JBC July 2002), Fluehmann et al. (US 6,784,207), and Cincotta et al. (US 5,714,519) beneficially teach compositions and methods for the treatment of diabetes comprising EGCG, phytanic acid and pantethine and are relied upon for the reasons set forth above.

Fischer (US 5,599,835) beneficially teaches lipoic acid as a treatment for diabetes (see e.g. abstract). Fischer further teaches a method for the treatment of diabetes comprising administering to a person in need thereof an effective amount of a medicinal food comprising lipoic acid (see e.g. claim 1).

Pistolesi beneficially teaches a composition for treating aging processes and related compositions, including diabetes. Pistolesi further teaches that the composition comprises policosanol (see e.g. page 1). Pistolesi also discloses that the composition may be used in functional foodstuffs (see e.g. claim 19).

Eriksson beneficially teaches the use of coenzyme Q_{10} in a treatment for diabetes (see entire document and Discussion).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the ingredients beneficially taught by Chan, Law et al., Fluehmann et al., Cincotta et al., Fischer, Pistolesi, and Eriksson to make a food or beverage comprising EGCG, pantethine, phytanic acid, lipoic acid, policosanol and coenzyme Q_{10}. A person of ordinary skill in the art would have been motivated to combine these ingredients because, as discussed above and in the instantly cited references, the use of these compounds for the same purpose (treatment of diabetes) was known at the time the claimed invention was made. A person of ordinary skill in the art would have further been motivated to add the composition to a food or beverage since this is a widely known modification in the nutritional supplement art and since it is disclosed by Fischer and Pistolesi that a diabetes treatment is in the form of a food.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

In response to applicant's arguments in the reply filed 20 February 2008 that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would recognize that since Chan, Fluehmann et al., and Cincotta et al. teach that EGCG, phytanic acid and pantethine are useful in the treatment of diabetes, it would be advantageous to combine them and use the combination for the same purpose.

Applicants further argue that it is not apparent why one of ordinary skill in the art would combine the teachings of Fluehmann, Chan and Cincotta. This is not persuasive. As previously stated, a person of ordinary skill in the art would have recognized that because Fluehmann, Chan and Cincotta each teach treating diabetes, that the treatments could be combined to treat diabetes and would have been motivated to do so since it is well known that ingredients with the same use can be combined to form a new composition with the same use. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose (as well as to use the combination for that purpose). The idea for combining

them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients.

Applicants also argue that a reasonable expectation of success is not found in the cited documents. This is not persuasive, as the expectation of success would come from the conclusion that a person of ordinary skill in the art would draw from the disclosures of the prior art. Because the cited references teaches that EGCG and pantethine and phytanic are useful for treating diabetes, a person of ordinary skill in the art would conclude that EGCG and pantethine and phytanic could be combined to treat diabetes. An explicit suggestion to combine the cited prior art references under 35 U.S.C. 103(a) need not be found in the references themselves. It is noted that KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, -- USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at <<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>>). Rather, the rationale for the instant finding of obviousness is that the claims would have been obvious because a person of ordinary skill has good reason to pursue the known

options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Thus, because a person of ordinary skill in the art would have known that that EGCG, pantethine and phytanic acid could all be useful in treating diabetes, it would have been obvious and within the technical grasp of a person of ordinary skill in the art to use the instantly claimed combination of pantethine, EGCG and phytanic acid to treat diabetes.

Applicants also argue that because Chan et al. discloses a laundry list of potential indications for which EGCG could be implicated and that Chan's only mention of diabetes in the specification refers to insulin-dependent diabetes and does not include type II diabetes. Applicant's argument that Chan et al. does not specifically teach EGCG for treatment of diabetes, but rather includes it in a laundry list is not persuasive. Claim 2 of Chan et al. is drawn to a method of treating diabetes. Applicants also argue that Chan et al. is essentially drawn to treating type I diabetes, while Cincotta et al. and Fluehmann et al. are drawn to treating type II diabetes, therefore, it would not be obvious to combine the teachings. This is not found persuasive. Both type I and type II diabetes share the common problem that blood glucose is increased due to an inability of insulin to process glucose, which is either due to a lack of insulin (type I diabetes) or a insulin resistance (type II). The common symptom of hyperglycemia is known in the art and is evidenced by Pierce (British Journal of Sports Medicine 1999). Pierce states that diabetes is a group of chronic metabolic disorders characterized by hyperglycemia resulting from a relative deficiency in insulin through either reduced insulin secretion or reduced insulin action or both (see e.g. page 161). Applicants argue

that because Fluehmann et al. and Cincotta et al. teach that phytanic acid and pantethine are useful for treating type II diabetes and Chan et al. mentions treating type I diabetes with EGCG, it would be self defeating to combine these components for treatment of both type I and type II diabetes because Fluehmann and Cincotta teach that hyperinsulinemia can be reduced with phytanic acid and pantethine. This is not persuasive because Law et al. discloses that EGCG can also lower blood insulin levels (see e.g. page34933). In addition, as previously stated, both diseases share the same characteristic problem (hyperglycemia). Cincotta teaches that pantethine reduces hyperglycemia (see e.g. col 5, lines 6-8), Fluehmann teaches that phytanic acid provides enhanced serum glucose clearance (see e.g. col 6, lines 46-53), and Law et al. teaches that EGCG lowers blood glucose levels (see e.g. pages 34933 and page 34939). Since high blood glucose is a common symptom to both types of diabetes, it would have been obvious to a person of ordinary skill in the art to use EGCG in combination with other treatments for diabetes in order to achieve an enhanced anti-diabetic effect. Applicants have summarized the teachings of Chan et al., Fluehmann et al. and Cincotta et al. and have suggested possible mechanisms by which each of the disclosed treatments for diabetes using EGCG, phytanic acid and pantethine may act. These arguments are not persuasive, however, as these mechanisms are not explicitly disclosed by the references. Please note also that Cincotta et al. teach that patients of both type I and type II diabetes may share the problem of insulin resistance (see e.g. col 1, lines 47-56) and Peirce teaches that both types of diabetes are characterized by hyperglycemia resulting from a relative deficiency in insulin, either through reduced

insulin secretion or reduced insulin action, or both (see e.g. page 161, second para). Treating diabetes is disclosed by Chan et al. (see e.g. claim 2), Law et al. (see e.g. page 34939), Fluehmann et al. (see e.g. abstract) and Cincotta et al. (see e.g. col 5, lines 5-10). Therefore, one of ordinary skill in the art at the time the claimed invention was made would recognize that both conditions would benefit from the administration of EGCG, pantethine and phytanic acid since each are taught separately in the art to be useful for the treatment of diabetes and because both types are characterized by the same symptom (hyperglycemia).

Therefore, the rejection is deemed proper and is maintained.

Applicant's arguments concerning Chan et al., Fluehmann et al., and Cincotta et al. are discussed above. Applicants argue that it would not be obvious to further add, lipoic acid, policosanol and coenzyme Q_{10} to a composition in order to treat diabetes as instantly claimed. This is not persuasive, however, as Fischer, Pistolesi, and Eriksson each disclose that lipoic acid, policosanol and coenzyme Q_{10} are useful in treating diabetes. Therefore one of ordinary skill in the art would be motivated to combine these components with EGCG, phytanic acid and pantethine, which are known in the art to be useful for treating diabetes in order to form a food supplement which is useful in treating diabetes. Applicants have further argued that based on the disclosures of Chan, Fluehmann and Cincotta, it would defy common sense to administer EGCG, phytanic acid and pantethine concomitantly. This is not persuasive and this argument has been

addressed above, as both types of diabetes share the same problem of hyperglycemia. Applicants also argue that nothing in Fischer, Pistolesi and/or Eriksson offers anything to fill in the gap in the combination of Chan, Fluehmann and Cincotta. This is not persuasive, as Fischer, Pistolesi and Eriksson are relied upon for their disclosure of the use of lipoic acid, policosanol and coenzyme Q_{10} for treating diabetes. In combination with the teachings of Chan, Law, Fluehmann and Cincotta, the disclosure of Fischer, Pistolesi and Eriksson render the instantly claimed invention obvious because all are drawn to treating diabetes. A person of ordinary skill in the art would have had a reasonable expectation of success in using ingredients known in the art to treat diabetes in combination in order to treat diabetes more effectively. A person of ordinary skill in the art would have had a reasonable expectation of success in using these ingredients to treat both type I and type II diabetes, based upon the fact that the characteristic problem of hyperglycemia is common to both types of diabetes, whether it is the result of a lack of insulin secretion or a lack or the ineffectiveness of insulin that is present.

The rejection is deemed proper and is maintained.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655

Melenie McCormick
Examiner
Art Unit 1655